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| 23702 7590 03/13/2008<br>Bausch & Lomb Incorporated<br>One Bausch & Lomb Place<br>Rochester, NY 14604-2701 |             |                      |                     |                  |
| EXAMINER<br>STIGELL, THEODORE J  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/664,837  
Filing Date: September 17, 2003  
Appellant(s): PERKINS ET AL.

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Michael L. Smith  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 7/13/2007 appealing from the Office action mailed 1/17/2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

|              |                    |         |
|--------------|--------------------|---------|
| 5,997,562    | Zadno-Azizi et al. | 12-1999 |
| 6,332,874 B1 | Eliason et al.     | 12-2001 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 5-6, 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi et al. (5,997,562) in view of Eliason et al. (6,332,874).

The examiner's interpretation of the claims rejected above is now presented. The examiner is interpreting the term "phacoemulsification cannula or needle" as a tubular element that is capable of aspirating and irrigating and is also capable of being vibrated by an ultrasonic handpiece. The applicant has not provided in the specification a special definition of the term "phacoemulsification cannula" in which any special structural feature is defined. From paragraph [0004] of the applicant's specification, a broad but reasonable interpretation of "phacoemulsification cannula or needle" can be construed as a tubular element that is capable of aspirating/irrigating and is also capable of being vibrated by an ultrasonic handpiece.

Claim 1 further recites that the phacoemulsification cannula has a threaded hub for engagement with a phacoemulsification surgical instrument. The examiner is interpreting this to mean that the cannula structurally requires a threaded hub that is capable of being engaged with a phacoemulsification surgical instrument. Claims 5 and 9 recite a proximal end that is structured for attachment to a phacoemulsification surgical instrument. The interpretation is similar in that these claims only structurally recite a proximal end that functionally has the capability to attach to a phacoemulsification surgical instrument.

Claim 1 further recites that "ultrasonic energy is transferred from the surgical instrument to the needle during surgery". This limitation is purely functional and does not denote any structural feature. The needle only has to have the capability to transfer at least a small amount of ultrasonic energy a small distance, which is a very broad limitation that can be met by almost any material commonly used in the medical arts.

Zadno-Azizi et al. discloses a phacoemulsification cannula (See Figure 1, the device is tubular and therefore is capable of irrigating/aspirating and is made of a polymeric material or metallic hypotube and is therefore capable of being vibrated by an ultrasonic handpiece) comprising a hub (3) that is capable of being engaged with a phacoemulsification surgical instrument, an elongated phacoemulsification needle (12) having a proximal end attached to the hub and a distal end, wherein the needle has a first inner diameter/bore (14a) extending from the distal end toward the proximal end that is larger than the second inner diameter/bore (14b) and wherein a transition region (21) from the first diameter to the second is located closer to the proximal end than the

distal end, and wherein the cannula is capable of transferring some ultrasonic energy at least a small distance from a surgical instrument.

Zadno-Azizi et al. shows a luer lock 3 on the hub. Zadno-Azizi et al. teach that connectors can be made in different ways. Zadno-Azizi et al. show one embodiment to be a luer connector and mentions others such as friction fit, or a ridged-groove connection. Zadno-Azizi al. realizes that any connector is possible to provide for a connection between a hub and another device. Eliassen et al. (US 6,332,874) disclose a catheter/tubular system which provides for a threaded connection 24 at the proximal end to another device. Specifically, Eliassen teaches luer connector threads 24 formed on a coupling hub 26. It would have been obvious to one of ordinary skill in the tubular devices in the medical arts to modify or substitute the luer connector of Zadno-Azizi et al. with a luer connector which is threaded as taught by Eliassen et al. in order to provide a secure connection between elements.

#### **(10) Response to Argument**

The applicant's arguments filed on 7/13/2007 have been considered and are not persuasive.

The applicant contends that the only similarity between the claimed invention and the device of Zadno-Azizi is that they both have a larger distal bore, a smaller proximal bore, and a transition region there between located closer to the proximal end. The applicant contends that the device of Zadno-Azizi would not be capable of ultrasonic energy transmission because such a transmission "would shake it (the Zadno device) apart in short order (page 5, line 4 of the appeal brief). The examiner believes that this

statement supports the rejection in that the applicant seems to recognize that at least some ultrasonic energy could be transmitted through the device. It is the examiner's position that independent claim 1 only requires the capability of a small transmission of ultrasonic energy. The applicant further argues that "even if the assembly (the Zadno device) were one piece of polymer tubing it is not clear that ultrasonic energy **could be effectively** transmitted through such a sheath" (page 5, lines 8-9 of the appeal brief). The examiner notes that there is no limitation recited in the claims regarding effective transmission of ultrasonic energy. The examiner concludes that the Zadno-Azizi device is capable of transmitting at least some ultrasonic energy and is therefore similar to the recited invention and is not irrelevant to the instant application.

In response to applicant's argument that Zadno-Azizi is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the device of Zadno-Azizi is in the field of the applicant's endeavor in that the applicant is merely claiming a cannula/needle that can be used for irrigation/aspiration and has the capability of being vibrated by an ultrasonic handpiece. The device of Zadno-Azizi is hollow and can therefore be used for irrigation/aspiration and is also certainly capable of being vibrated, at least in a small amount, by an ultrasonic handpiece. Furthermore, Zadno-Azizi discloses a hub (proximal end) that can be engaged or attached with a phacoemulsification surgical instrument. The applicant is

reminded that the surgical instrument is not required by the claim and a user could certainly attach one to the hub of Zadno-Azizi if they so desired.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references is that while Zadno-Azizi contemplates different connection configurations, Eliason specifically teaches that threaded connections are useful in providing secure connections in the medical arts. One skilled in the art would recognize that secure connections between fluid handling devices is desirable to avoid problems such as leakage and contamination.

In response to the applicant's contention that the examiner has given little or no weight to the functional language, the examiner respectfully disagrees. Please see the rejection above for a complete interpretation of the functional language. It is the examiner's position that weight has been given to the functional language, but the functional language does not convey any structural limitations not shown in the prior art.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.



Art Unit: 3700

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Theodore J Stigell/

Examiner, Art Unit 3763

Conferees:

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763

/Janet C. Baxter/

TC 3700 TQAS